UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

JN

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/813,776	03/07/97	CAVALIERE VESELY R	7063-001-0

HM22/0125

OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT
FOURTH FLOOR
1755 JEFFERSON DAVIS HWY
ARLINGTON VA 22202

EXAMINER	
MINNIFIELD,N	
ART UNIT	**PAPER NUMBER**
1645	7

DATE MAILED: 01/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/813,776	Applicant(s) VESELY ET AL
	Examiner N. M. Minnifield	Group Art Unit 1645

☒ Responsive to communication(s) filed on *Oct 29, 1998* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-36* is/are pending in the application.

Of the above, claim(s) *12-36* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☒ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: *No English translation of certified copy received* .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-11, in Paper No. 6 is acknowledged. The traversal is on the ground(s) that Groups I and II are combination and subcombinations; bacteria of Group I are the subcombination and the pharmaceutical compositions of Group I are the combination of the bacteria of Group I and pharmaceutical carrier. Applicants assert that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between any of Groups I-III. Upon further review, the following reasoning is set forth for maintaining that a restriction is required. Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as for making antibodies; invention I has separate utility such as for tissue culture or in diagnostic assays. See MPEP § 806.05(d). The requirement is still deemed proper and is therefore made FINAL.

2. Claims 12-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

3. The disclosure is objected to because of the following informalities: the specification at pages 7 and 8 refer to specific claims and claim numbers. Applicants should not make such references to specific claim numbers since these particular claims may or may not actually be deemed patentable, allowed and printed in the issued patent. Appropriate correction is required.

4. Claims 4-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that bacterial strains set forth in the claims are required to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of each bacterial strain. See 37 C.F.R. 1.802.

The specification does not provide a repeatable method for obtaining the bacterial strains as claimed and it does not appear to be readily available material. Deposit of the bacterial strains would satisfy the enablement requirements of 35 U.S.C. § 112. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability

to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposits have not been made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposits will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

© the deposits will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

5. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The claims are directed to descendants, mutants and derivatives thereof of a bacterial strain preserving the activities of dehydroxlase (less than 50%) and bile acid deconjugation (less than 50%). However, the specification provides no guidance to the skilled artisan with regard to obtaining the descendants, mutants and derivatives thereof of a bacterial strain preserving the activities of dehydroxlase (less than 50%) and bile acid deconjugation (less than 50%). There is no enablement set forth in the specification, nor is there clear written description for such descendants, mutants and derivatives thereof of a bacterial strain preserving the activities of dehydroxlase (less than 50%) and bile acid deconjugation (less than 50%).

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: It was not executed in accordance with either 37 CFR 1.66 or 1.68. There is no date of execution with regard to the signatures of the inventors. DK

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file; however an English translation of the certified copy has not been filed.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 and 2 are rejected under 35 U.S.C. 102(b, d, or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saito et al (5516684 or EP 0671468) in light of Salvioli et al.

It is noted that Saito et al (5516684) is rejected under 102(e) and Saito et al (EP 0671468) is rejected under 102(b or d).

Saito et al (5516684), for example, disclose a gram positive bacterial strain which does not exhibit deconjugation of bile acids (abstract). Saito et al also disclose bacteria that "...exhibits lowering of cholesterol in blood without exhibiting deconjugation of bile acids, thereby not forming secondary bile acids..." (col. 2, l. 46-50). The bacteria do not produce the secondary bile

acids since the bacteria do not exhibit deconjugation of bile acids (col. 5); therefore there is no dehydroxylase activity.

With regard to the dehydroxylase activity, it is noted that Salvioli et al disclose that "[U]nder normal conditions the deconjugation of bile acids occurs in the large bowel and perhaps in the terminal ileum; unconjugated bile acids entering the large bowel are 7 -dehydroxylated by anaerobic bacteria to yield secondary bile acids." (p. 80, col. 1). The secondary bile acids are dehydroxylated by dehydroxylase.

The claimed invention is anticipated by the prior art of Saito et al. The prior art, Saito et al, anticipates the claimed invention by disclosing the bacterial strains with the same or similar characteristics as claimed. The bacterial strains in the prior art are believed to inherently possess properties which anticipates the claimed invention or if they are not the same the bacterial strains of Saito et al, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the bacterial strains of the prior art are evidenced to meet the limitations of the claimed bacterial strains, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' bacterial strains with the bacterial strains of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the bacterial strains of the prior art does not possess the same material structural and functional characteristics of the claimed bacterial strains) See In re Best, 562 F.2d 1252, 195

USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Determination of characteristics which vary depending on the method of analysis, such as enzymatic activity, must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent.

13. No claims are allowed.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield
January 14, 1999

NITA MINNIFIELD
PRIMARY EXAMINER